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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,460	09/11/2003	Robert Boock	022956-0223	7148

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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08/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/661,460

Applicant(s)

BOOCK ET AL.

Examiner

Jeffrey G. Hoekstra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 22 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 05/22/2007 the following reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-3, 5-7, 10-16, and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockmeier (US 5,195,956) in view of Altman et al (WO 99/58066). Stockmeier discloses the claimed tissue harvesting invention including the following:

4. For claim 1, Stockmeier discloses a tissue extraction and maceration device, comprising: an outer tube (1) with an open distal end; a shaft (3 and 12) disposed within said outer tube articulating between a first-proximal (R) and second-distal (A) positions operably exposing the distal end of the shaft from the outer tube, as best seen in Figure 1; a tissue harvesting tip (4 and 5) disposed on the distal end of said shaft for excising tissue; and a cutting member (14) coupled to said shaft proximal to the tissue harvesting tip.

5. For claims 5-7, Stockmeier discloses a tissue extraction and maceration device, wherein the open distal end of the outer tube is defined by an angled edge wall that is angled with respect to a longitudinal axis of the outer tube, as best seen in Figure 1, said angle capable of being about 40 degrees.

6. For claims 10 and 11, Stockmeier discloses a tissue extraction and maceration device, wherein the cutting member (14) comprises at least one curved blade member extending radially from the shaft, as best seen in Figure 2.

7. For claim 12, Stockmeier discloses a tissue extraction and maceration device, wherein the tissue harvesting tip (4 and 5) comprises a cone-shaped member (4) having a plurality of cutting teeth (5) formed on an outer surface thereof, as best seen in Figure 1.

8. For claim 13, Stockmeier discloses a tissue extraction and maceration device, wherein the tissue harvesting tip (4 and 5) comprises a substantially semi-cylindrical housing (4) having a cutting surface (5) formed around a periphery thereof, as best seen in Figure 1.

9. For claims 14-16, Stockmeier discloses a tissue extraction and maceration device, wherein the tissue harvesting tip (4 and 5) is adapted to penetrate tissue and remove a predetermined tissue volume when articulating from proximal and distal positions (column 1 lines 29-62 and column 2 lines 43-48), said predetermined tissue volume capable of being about 0.9 cm^3 .

10. For claims 22-24, Stockmeier discloses a tissue extraction and maceration device, wherein the tissue harvesting tip (4 and 5) operably connected to said shaft is adapted to extend beyond the outer tube by a predetermined distance (column 2 lines 43-48), said predetermined distance capable of being about 3 mm.

11. For claim 25, Stockmeier discloses a tissue extraction and maceration device, wherein the outer tube is adapted to be coupled to a vacuum pump effective to draw tissue through at least a portion of the outer tube (column 2 lines 28-29).

12. Thus for claims 1-3, 5-7, 10-16, and 21-25, Stockmeier discloses the claimed tissue harvesting invention except for explicitly disclosing that (a) a cutting member disposed proximal the tissue harvesting tip is effective to macerate a tissue sample excised by the tissue harvesting tip, (b) a biasing element proximally biases the shaft and a trigger mechanism connected to a shaft overcome said biasing element, and (c) a motor, typically electric or pneumatic, coupled to the shaft rotates at speeds ranging from about 100 to 5000 rpm. Altman et al teaches (a) a cutting member (59) disposed proximal the tissue harvesting tip (38) effective to macerate a tissue sample excised by the tissue harvesting tip, (b) a biasing element (65) biasing the shaft proximally and a trigger mechanism (53) connected to a shaft (12 and 55) that overcome said biasing elements (page 11 lines 10-22), and (c) a motor (24), typically electric or pneumatic, coupled to the shaft capable of rotating at speeds ranging from about 100 to 5000 rpm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Stockmeier, with the cutting member, biasing, trigger elements, and motor as taught by Altman et al for the purpose of increasing the efficacy of a tissue extraction and maceration device by configuring a tissue extraction and maceration device for increased patient safety and increased user operability during advanced surgical procedures necessitating tissue extraction and maceration.

13. Claims 4 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockmeier in view of Altman et al and in further view of Shapira (US 6,358,252). Stockmeier in view of Altman et al discloses the claimed tissue harvesting invention except for explicitly disclosing the open distal end is configured to form a seal with a tissue surface or is defined by an angled edge wall further comprising ridged surface features. Shapira teaches a tissue harvesting device (10) comprising an open distal end configured to form a seal with a tissue surface and an angled edge wall including surface features, or ridges (62), as best seen in Figures 2 and 4. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Stockmeier in view of Altman et al, with the tissue sealing and surface ridges as taught by Shapira for the purpose of increasing the efficacy of a tissue extraction and maceration device by configuring a tissue extraction and maceration device for increased patient safety and increased user operability during advanced surgical procedures necessitating tissue extraction and maceration.

14. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockmeier in view of Altman et al and in further view of Majlessi (US 5,871,454). Stockmeier in view of Altman et al discloses the claimed tissue harvesting invention except for a sizing screen configured with openings comprising a diameter of 0.7 – 1.3 mm. Majlessi teaches a tissue-harvesting device (10) with permeable membrane (44") for filtering larger particulate matter, said permeable membrane capable of having openings with a diameter of 0.7 – 1.3 mm. It would have been obvious to one having

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ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Stockmeier et al in view of Altman et al, with the screen as taught by Majlessi for the purpose of increasing the efficacy of a tissue extraction and maceration device by configuring a tissue extraction and maceration device for increased patient safety and increased user operability during advanced surgical procedures necessitating tissue extraction and maceration.

Response to Arguments

15. Applicant's arguments filed 05/22/2007 have been fully considered but they are not persuasive. Applicant argues the 35 U.S.C. 103(a) rejections of claims 1-3, 5-7, 10- as being unpatentable over Stockmeier in view of Altman. Specifically arguing it would not have been obvious to modify the device as taught by Stockmeier because (a) it cannot be modified to include a cutting member located proximal to a harvesting tip as such a modification would render the device inoperable and (b) it is not used for harvesting tissue and the cutting member would serve no purpose. The Examiner disagrees, maintains the rejection, and notes the following:

16. In response to applicant's argument that (a) the device as taught by Stockmeier cannot be modified to include a cutting member located proximal to a harvesting tip as such a modification would render the device inoperable, the Examiner notes it is not required that the prior art disclose or suggest the properties newly-discovered by an applicant in order for there to be a prima facie case of obviousness. See *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897, 1905 (Fed. Cir. 1990). Moreover, as long as some motivation or suggestion to combine the references is provided by the prior art taken as

a whole, the law does not require that the references be combined for the reasons contemplated by the inventor. See *In re Beattie*, 974 F.2d 1309, 24 USPQ2d 1040 (Fed. Cir. 1992); *In re Kronig*, 539 F.2d 1300, 190 USPQ 425 (CCPA 1976) and *In re Wilder*, 429 F.2d 447, 166 USPQ 545 (CCPA 1970). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. *In re Bozek*, 416 F .2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

17. In response to applicant's arguments (a) against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

18. In response to applicant's argument that (b) the device as taught by Stockmeier in view of Altman is not used for harvesting tissue and the cutting member would serve no purpose, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

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capable of performing the intended use, then it meets the claim. In this case, as claimed Stockmeier is effective to macerate tissue.

19. In response to applicant's argument (b) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., collecting tissue) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

20. In response to applicant's argument that (b) Stockmeier is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Stockmeier is concerned with a medical device for cutting tissue.

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

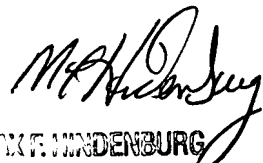
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra
Examiner, Art Unit 3736


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